



Document Processing Desk (DCI/PRD)
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U.S. Environmental Protection Agency
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July 30, 2018

Bayer CropScience
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P. O. Box 12014
RTP, NC 27709
Phone: (919) 549-2000

Attention: Brian Kettl, Registration Review

Subject: Tebuconazole – Generic ID# GDCI-128997-1598
Request for Extension for DCI studies

Dear Mr. Kettl:

On December 23, 2017, we submitted our 90-day response to the Tebuconazole Reregistration Eligibility Decision for Generic Data Call-In (received on September 14, 2017). Due to challenges with staff resources and one study design (regurgitation challenges associated with the avian study), Bayer is requesting an extension of the submission date for three (3) of the requested studies:

1. 850.4500. Algal Toxicity.
2. 850.4550. Cyanobacteria (*Anabaena flos-aquae*) Toxicity.
3. 850.2100. Avian acute oral toxicity test.

Regarding the avian acute oral study, a range-finder was completed for the acute oral study using the canary. Three birds were used at 3 test levels, 2000, 624 and 200 mg/kg and were dosed by gelatin capsule. Regurgitation occurred in all birds. Due to regurgitation, it is unlikely that an acceptable avian acute oral study can be conducted. Bayer proposes an avian dietary study following 850.2200 in lieu of the avian acute oral study (850.2100) for tebuconazole.

The studies are presently contracted with EAG, Inc. laboratories, and have an expected report delivery to EPA by April 14th, 2019, according to current EAG, Inc. laboratory capacities.

Therefore, Bayer is requesting an extension of the date for submission for these three (3) studies to 14-April-2019 (see Table 1). Since the submission deadline for other studies in the DCI is September 14, 2019, and the three studies in Table 1 can be delivered to EPA well in advance of Sept 2019, we believe the extension would have minimal impact on the Tebuconazole registration review timeline.

Please find below a summary Table of the studies and requested submission dates.

Table 1. Studies for which a deadline extension is requested

Guideline	Test	Original date for Submission	Requested date for submission
850.4500	Algal Toxicity	14-Sep-2018	14-April-2019
850.4550	Cyanobacteria (Anabaena flos-aquae) Toxicity	14-Sep-2018	14-April-2019
850.2200 (in lieu of 850.2100)	Avian dietary toxicity test (in lieu of Avian acute oral toxicity test)	14-Sep-2018	14-April-2019

We appreciate the Agency's time in considering these extension requests and look forward to feedback on our request. Should additional information or clarification be needed, please contact me by phone at (919) 549-2631 or by e-mail at jessica.fernandez@bayer.com.

Sincerely,



Jessica Fernandez
Registration Manager